REMARKS

This is amendment is responsive to the Office Action of January 18, 2007. Reconsideration and allowance of claims 6, 7, 12-23, 25, and 26 are requested.

The Office Action

Claims 1-13 and 15-24 stand rejected under 35 U.S.C. § 102 as being anticipated by Grzeszczuk (US 2002/0077543).

Claim 14 stands rejected under 35 U.S.C. § 103 over Grzeszczuk in view of Kienzle (US 6,697,664).

Claim 25, which has not been rejected on art, is understood to contain allowable subject matter.

The Prior Art

When performing image-guided surgery, various mascinations are typically performed on a patient by patient basis in order to determine an alignment between the surgical tool and the patient and the image. By contrast, the present application discloses a technique which does not require individualized calibration for each patient.

In the "Background" section, Grzeszczuk discusses an acknowledged prior art stereotaxy frame (paragraphs [0012] et seq.). In framed stereotaxy, a ring is affixed to the patient's skull using surgical screws. This ring typically carries a series of gradiated markings and functions as a track for a surgical tool support or tool guide. The frame with associated fiducials is imaged in a CT scanner. After the patient leaves the CT scanner, the surgeons plan the surgery. Because the surgical frame is rigidly attached to the skull, it holds its position as the patient moves about.

Once the surgery has been planned, the patient returns. Using a biopsy as an example, the surgeon uses the stereotaxy frame to mount a needle guide extending along the planned biopsy trajectory. The guide is also used as a drill guide to drill through the patient's skull. Typically, a stop is placed on the biopsy needle and it is inserted the planned distance along the trajectory.

It should be noted that there is typically no verification with a CT scanner that the biopsy needle has, in fact, reached the target.

Grzeszczuk points out the difficulties with framed stereotaxy procedures and proposes a completely different procedure which is different from and not an add-

on to framed stereotaxy-type procedures. Thus, the Examiner, by trying to combine the framed stereotaxy with the preferred procedure of Grzeszczuk is actually performing a § 103 combination between two techniques, which Grzeszczuk himself, teaches are incompatible alternatives.

In Grzeszczuk's primary technique, he generates a CT image of a region of the subject at a location remote from the surgical site. He then uses an x-ray fluoroscope **14, 16** to generate fluoroscopic, projection images. First, Grzeszczuk generates a pair of fluoroscopic projection images along two different directions, e.g., along a vertical and a horizontal axis. He uses these two projections to align the patient and the fluoroscopic camera with the CT image. During the procedure, the fluoroscopic device may be moved to different positions or angular orientations. However, due to tracking devices **16a**, the position of the fluoroscopic imaging device relative to the CT image remains known.

Next, two fluoroscopic views along different directions are generated of the surgical tool and projected into the CT data reference frame (paragraph [0041]). This enables the tool to be visualized on the 3D CT model. Tracking devices **18a** enable the location and orientation of the tool to be tracked as it moves from this initial calibration position.

The Examiner Has Failed to Cite the "Best Reference"

There are numerous patents and other references which are directed to or otherwise show the details of typical stereotaxy frames. It is submitted that if the Examiner wants to rely on a prior stereotaxy frame as either a primary or teaching reference, she should cite one of the many prior patents that clearly describe such a structure and its use. Through such a full understanding of framed stereotaxy, it will become apparent that there is no motivation to incorporate such a frame into the Grzeszczuk frameless stereotaxy system.

The Present Application

Most image-guided surgery techniques align the surgical tool with the diagnostic image. Typically, this requires the surgeon to perform registration steps to register the patient to the images and the surgical tool to the images. This slows patient throughput and uses a significant amount of expensive, skilled labor to perform the registration processes. The Examiner's applied reference of Grzeszczuk is one example of such a technique.

The present application does a pre-registration of the scanner, the tracking system, and the images generated by the scanner. Once this preregistration is established, the computer can perform the registration and determined transforms between the surgical tool and the diagnostic images without manual intervention by the surgeon.

It will be noted that the present application proposes a more elaborate calibration routine in which a larger number of transforms between elements are determined. Although the present process may seem more complex, the work is done by the computer. The surgeon has much less participation in the registration and calibration process.

One striking difference over Grzeszczuk is the use of a scan calibrator **42** which includes fiducials **46** which are imaged by the imaging device and markers **44** through which the tracking system monitors the position of the calibrator. Using the markers **44** and markers **37** on the scanner, one can determine the transform between the position of the calibrator and the position of the scanner. Further, by comparing the now known position of the fiducials when they were imaged, the transform between the generated image and the calibrator can be determined. Since the position of the calibrator relative to the scanner was already determined, the transform between the image and the scanner is now known, even when the calibrator is removed. Thus, this calibration procedure can be performed once during initial set-up of the scanner (although more frequent calibration checks are always advisable).

Using the patient markers **37**, the tracking system can determine the position of the patient during the patient imaging process, enabling the computer to generate a transform between the patient and the anatomical image using the above-discussed transforms. When the patient is moved out of the imaging region of the scanner, the patient tracker moves with it. The computer recalculates the transform between the patient and the reconstructed image for the new patient position. The

tracking system also uses the instrument tracker **31** to track the instrument **30** in the frame of reference of the tracking system. However, with the scanner tracker **34** and the patient tracker **32** already located in the frame of reference of the tracking system, the relative position of the instrument **30** is readily determined as is the transform between the instrument and the image.

It will be noted that the surgeon can simply pick up the instrument **30** and perform the surgical procedure without performing patient-specific calibration steps.

Thus, although the computer system has calculated a large number of transforms, the surgeon has not needed to perform any calibration or registration steps.

The Claims Distinguish Patentably Over the References of Record

Claim 6 has been placed in independent form. Claim 6 calls for scanning a scanner calibrator. Grzeszczuk discloses no scanner calibrator. Both the preferred Grzeszczuk technique described in the "Detailed Description" and the acknowledged prior art stereotaxy frame involve calibrating a subject and the surgical instrument with the patient's anatomical images without the intermediary of registering any of the above relative to the CT or other scanner that generated the anatomical images. It will be noted that the fluoroscope **14, 16** of Grzeszczuk does not generate the diagnostic images. The diagnostic images are generated by a CT scanner (paragraph [0037]). The fluoroscope is used as an alignment tool to help align the patient, the instrument, and the current position of the instrument with the previously generated CT data.

Claim 6 calls for determining a position of the scanner calibrator while images of it are acquired. There is no corresponding step in Grzeszczuk.

Claim 6 calls for determining a transform T_c between the scanner calibrator and a scanner tracker. Again, having no scanner calibrator, Grzeszczuk has no ability to generate such a transform.

Claim 6 further calls for generating a transform T_i that maps the location of at least one fiducial of the scanner calibrator to a position of the representation of that at least one fiducial in an acquired calibration image. Again, Grzeszczuk does not use a scanner calibrator and does not generate the second transform.

Further, claim 6 calls for calculating a transform T_s between the scanner tracker and the image based on the transform T_c and T_i. Having neither calculating

nor having the data to calculate transforms T_c and T_i, Grzeszczuk makes no suggestion of calculating transform T_s.

Claim 6 goes on to set forth additional calculations and determinations which are neither made nor fairly suggested by Grzeszczuk. Accordingly, it is submitted that **claim 6** is not anticipated by Grzeszczuk.

Claim 12 again calls for a scanner calibrator. Grzeszczuk has no such scanner calibrator. Claim 12 further calls for determining three transforms which rely on the use of the scanner calibrator. Having no scanner calibrator, Grzeszczuk fails to anticipate the recited operations.

Accordingly, it is submitted that **claim 12 and claims 7 and 13-17 dependent therefrom** are not anticipated by Grzeszczuk.

Claim 18 calls for determining a transform between a calibration image of a scanner calibrator and a scanner. Having no scanner calibrator, Grzeszczuk does not anticipate claim 18.

Claim 18 goes on to use this determined transform or transforms derived therefrom to determine a current transform between the instrument and the anatomical images. Grzeszczuk teaches that a different technique should be utilized using fluoroscopic images generated with a separate imaging device rather than a scanner calibrator. Accordingly, it is submitted that **claim 18 and claims 19-23 dependent therefrom** are not anticipated by Grzeszczuk.

Claim 25, not standing rejected on prior art, is understood to be allowable.

Claim 25 calls for receiving an indication of a position of a patient tracker. The technique advocated by Grzeszczuk in the "Detailed Description" uses no patient tracker. The stereotaxy frame referenced in the "Background" of Grzeszczuk also has no tracker for tracking its position or the position of the patient. Because the stereotaxy frame is fixed to the patient by surgical screws, the relative position of the two is fixed and need not be tracked.

Further, claim 25 calls for determining a spatial position between the patient tracker and the scanner. Again, Grzeszczuk neither has nor needs a patient tracker in the present sense. Grzeszczuk determines the position of the patient relative to the CT scanner using shadowgraph **14, 16**. If one interprets the shadowgraph as the patient tracker, then it is submitted it would be improper to also consider it the scanner. In any case, Grzeszczuk does not teach or fairly suggest determining a

spatial relationship between the shadowgraph and the shadowgraph, and does not do this based on a known position of the shadowgraph.

Claim 25 calls for determining a spatial relationship between the patient tracker and at least one scanner image based at least in part on a known spatial relationship of the scanner relative to the scanner image. Again, Grzeszczuk does not have a patient tracker. Moreover, Grzeszczuk does not know or determine a spatial relationship between the CT scanner and the scanner image. If one now tries to interpret the shadowgraph **14, 16** as the scanner, then there is no known spatial relationship between it and the diagnostic image. Rather, a projection image comparing routine is utilized to try to determine such relationship.

Claim 25 calls for determining a spatial relationship between the instrument and the patient tracker. Again, Grzeszczuk does not have a patient tracker.

Claim 25 further calls for determining a spatial relationship between the instrument and the scanner image based on the aforediscussed determinations which are not made in Grzeszczuk. This prevents Grzeszczuk from making the claimed determination. As discussed above, Grzeszczuk determines the relationship of the instrument and the image in a different way which requires more time on the part of the surgeon.

Accordingly, it is submitted that **claim 25** is not anticipated by Grzeszczuk.

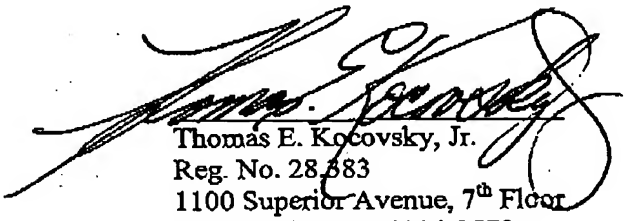
CONCLUSION

For the reasons set forth above, it is submitted that claims 6, 7, 12-23, 24, and 26 are not anticipated by Grzeszczuk. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is requested to telephone Thomas Kocovsky at (216) 861-5582.

Respectfully submitted,

FAY SHARPE LLP



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